1	UNITED STATES DISTRICT COURT
2	CENTRAL DISTRICT OF CALIFORNIA
3	EASTERN DIVISION-RIVERSIDE
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5	HONORABLE JESUS G. BERNAL, DISTRICT JUDGE PRESIDING
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7	UNITED STATES OF AMERICA,)
8	Plaintiff,)
9	vs.) No. EDCV 18-1005-JGB
10	CALIFORNIA STEM CELL TREATMENT) CENTER, INC., et al.,)
11	Defendants.)
12)
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14	REPORTER'S TRANSCRIPT OF ORAL PROCEEDINGS
15	Riverside, California
16	Monday, July 13, 2020
17	11:23 a.m.
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22	PHYLLIS A. PRESTON, CSR, FCRR
23	Federal Official Court Reporter United States District Court
24	3470 Twelfth Street Riverside, California 92501
25	stenojag@aol.com

1	APPEARANCES:
2	
3	For the Plaintiff: (Telephonically)
4	U.S. DEPARTMENT OF JUSTICE Consumer Protection Branch
5	By: NATALIE SANDERS ROGER GURAL
6	Trial Attorneys 450 5th Street, NW, Suite 6400-South
7	Washington, DC 20530
8	U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
9	FOOD & DRUG ADMINISTRATION By: MICHAEL SHANE
10	MICHAEL HELBING 10903 New Hampshire Avenue
11	Silver Spring, MD 20993-0002
12	
13	
14	For the Defendants:
15	VENABLE LLP By: CELESTE BRECHT
16	MATTHEW GURVITZ Attorneys at Law
17	2049 Century Park East, Suite 2300 Los Angeles, California 90067
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1 MONDAY, JULY 13, 2020; RIVERSIDE, CALIFORNIA 2 -000-THE CLERK: Calling No. 8 on the calendar, EDCV 3 18-1005-JGB, United States of America v. California Stem Cell 4 5 Treatment Center, Inc. 11:23 6 Counsel, please state your appearances for the 7 record. MS. SANDERS: Good morning. This is Natalie Sanders, 8 9 trial attorney with the United States Department of Justice in 10 Washington DC appearing on behalf of United States of America, 11:23 11 the plaintiff in this matter. 12 THE COURT: Good morning. 13 MS. SANDERS: Good morning. Joining me on this call, 14 Your Honor, is Federal DOJ trial attorney Roger Gural. He 15 started as my trial co-counsel on the matter. And also joining 11:24 16 us are two attorneys from the U.S. Food and Drug 17 Administration, Michael Shane and Michael Helbing, and they are serving as of counsel on this matter. 18 19 THE COURT: Very well. Thank you. And good morning 20 to you all. 11:24 21 MS. BRECHT: Good morning, Your Honor. Celeste 22 Brecht on behalf of the defendants. 23 MR. GURVITZ: Good morning, Your Honor. Matthew Gurvitz also on behalf of the defendants. 24 25 THE COURT: Good morning. The matter is on calendar 11:24

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today for the final pretrial conference. I assume that both
sides will be ready to proceed to this court trial on
July 28th; is that correct?
          MS. BRECHT: Yes, Your Honor.
          MS. SANDERS: Well, Your Honor, the Government
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certainly has been working diligently to prepare for trial and
we certainly are looking forward to conducting that trial very
shortly, but I did just want to flag that we do have some
concerns about an in-person trial if that were to be held in
the next two weeks.
                                                                 11:25
          THE COURT: About a what trial? You have some
concerns about a what trial you said?
          MS. SANDERS: An in-person trial. To the extent that
Your Honor is contemplating that all of the counsel and
witnesses would appear in person for the trial in Riverside, we
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do have some concerns about that, particularly in light of the
way the numbers seem to be trending in California right now.
                     Right. Well, I understand and share your
          THE COURT:
concerns, but I think there's things that we can do to assuage
your concerns. One is, counsel here for the defendant and
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every one present in court is wearing masks. That's mandatory
in my court. And any witnesses that testify will be wearing
masks. And there is enough room in this courtroom for everyone
to socially distance. So we are taking precautions. There are
markers in the seating that indicate the spacing that is
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1 required for people. Since we're not having the jury trial then those concerns regarding a jury are not present. 2 3 So if all of you are present, I guess that's four 4 attorneys, and you might have to like sit two in the front and 5 two in the back which may allow for social distancing. So I 11:26 6 think there's enough space in this courtroom to both have 7 everybody wear a mask and have everybody social distance while 8 the proceedings take place. So given that, are your concerns 9 any less or the same? 10 MS. SANDERS: We certainly appreciate the thought and 11:26 11 attention that Your Honor has put into thinking about how we 12 can do this. We would just flag whether now or a bit later 13 that we do have some witnesses who are not able to travel at 14 this time, and so we would need to talk about what arrangements 15 would be made for those individuals. 11:27 16 THE COURT: And they're not able to travel for what 17 reason? 18 MS. SANDERS: It varies. So we have one witness, 19 Michelle Forrester, she is one of our FDA investigators who 20 inspected defendants' facilities. She is out on leave and she 11:27 21 is not released by medical professionals to travel at this 22 time. 23 We have our CGMP expert. She is the person who is 24 going to testify to the facts that underlie our adulteration 25 charges, and she also is not able to travel at this time. 11:27

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And then finally, we have an additional expert, Dr. Doran Fink, and he actually has important duties related to the COVID-19 crisis, and so he does have a conflict with particular days, and then because of additional child care and other responsibilities that he has, he would prefer, if he has 11:28 to appear during the week of the 28th, to appear remotely. And specifically with respect to his conflicts, I can just inform the Court that he is on the CDC advisory committee on immunization practices, and he is an FDA-appointed representative for that, and he is out of pocket all day on 11:28 July 29th and cannot be replaced because of his role on that panel. So he does have a conflict with a particular day and then he also has a conflict with traveling more broadly. So that's at least three of the Government's witnesses who we anticipate have some challenges showing up in 11:28 person for the hearing. And additionally, you know, I would just underscore on their behalf that these folks would all be flying in. None of our witnesses are local to California. So these are going to be people coming in from Michigan, from Kansas, from Texas, New Mexico, Virginia, Maryland, and 11:29 Washington DC, and we do have concerns that some of them will have cold feet, so to speak, even if they were previously planning to testify in person. I think the most recent numbers showing that hospitalizations are going up, deaths are going up, cases of

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COVID infection are going up, and in the past week saw the
deadliest two days of the pandemic back to back in the State of
California with the state official cases now surpassing
300,000. It seems like we're actually perhaps in a worse
position than we were even back in March and earlier this year.
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          So I just want to be honest and transparent with the
Court and flag that, because I do think that's a concern for
every witness that will be traveling and remaining in
California and relying on public transportation, shared rides,
staying in hotels, and doing lots of things that increase their
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own exposure to possible infection and, you know, could result
in either illness or sickness to them or even worse, you know,
requiring everyone else associated with this trial to
quarantine for some period.
          So those are our concerns. It's not that we are not
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diligently preparing for trial and looking forward to trial.
think our concern is that we're in the middle of a pandemic
that seems to be getting worse, not better, and where,
potentially, we could look at other ways to do this trial that
would better protect people's health, or if we were able to
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postpone it briefly --
          THE COURT: Okay. I understand your concerns.
don't fault you or the witnesses for having such concerns
certainly. So the alternatives to that is either, as you said,
either postpone the trial or have some kind of way where the
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witnesses that you indicated would testify remotely by video instead of live in court.

I guess the first question I have is, would the defendants be opposed to such a procedure?

MS. BRECHT: Your Honor, we would be definitely opposed to continuing the trial given that this lawsuit has dramatically impacted my clients' ability to conduct their business, and it's been continued multiple times. We're cognizant of the health concerns and we've met and conferred extensively with the Government, and we have no objection to any witness or counsel appearing remotely, if they would like to do so for, you know, protecting health concerns.

THE COURT: Very well. So I think that's the way to go then, set up a system by which the witnesses that did not wish to appear in person can testify through video, and I think that's -- we have the capability of doing that here in the courtroom. And again, since it is a court trial and not a jury trial then a lot of the concerns that would normally be attendant to not in-person testimony are not present.

So are you then -- I guess the question comes back to the plaintiff, are you comfortable then with the idea that you would present at least some of your witnesses through video?

MS. SANDERS: Well, we certainly appreciate that accommodation, and if that's the way the Court wishes to proceed, we would welcome that opportunity and we would want it

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to be extended to any witness who has concerns and also any counsel on this matter that has a concern. I think that raises a question of how we would go about doing that and how we would work out the technical details. We've begun to give some thought to that, and I would just ask that we could have space and opportunity to have our technical people connect with the Court's technical people and make sure that we are able to do this in a seamless and as nondisruptive of a manner conducive to the conduct of the trial that Your Honor is expecting.

My co-counsel on this matter, Roger Gural, has given some thought to some of the issues, and certainly we've had discussions with defense counsel about some of the issues that we might be faced with, and I think that we would just need additional guidance from the Court to really make that a reality, particularly where a number of our witnesses would be doing this from home remotely.

THE COURT: Right. So I know it can be done because, again, the Court has that capability, and I can have my clerk and the Court's technical person consult with you and/or your staff to perhaps give a trial run and see whether or not it can be done as seamlessly as you say.

Also, if we run into some technical difficulties after the beginning of the trial, I'll be flexible in giving you time and/or resources to try to resolve those difficulties so the testimony you wish to present is, in fact, presented.

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So I think that sort of we have a working plan that we will proceed with the trial on the 28th, and both sides will have the flexibility to present any witnesses or counsel either in person or remotely through video. So I will keep that trial date and direct both parties to confer with my deputy clerk and, of course, staff, technical staff to make sure that all technical difficulties are addressed so we can proceed.

Now I know there are some motions in limine pending. I can tell you that all of the ones that have been submitted will be denied, so that may cut down on the issues for trial and the witnesses to be presented.

Normally in a case - and, again, this is difficult to do -- I would set a time limit for both sides to present their case or to respond to the other side's case. I'm not going to do that in this time because of, again, the difficulties we may have with the video and the fact that video testimony may take longer than usual just because of the remote nature of that testimony and the difficulties that we may encounter.

But I will advise you that it is a court trial, so if
I find that somebody is testifying either repetitively or
testimony which I find not helpful or germane to the issues
presented, I will ask you to speed it up and/or call your next
witness. So be very careful about what witness you elicit. I
saw the witness list. The plaintiff's witness list is just too
long. I don't anticipate that all of those people would

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    testify given what I think are the narrow issues in the case.
              So be conscious about which testimony you wish to
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    present and make sure that that testimony is relevant to the
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    issues of the case and not unnecessary background or
    unnecessary any relevant considerations such as the safety of
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    the procedure form. So we may cut down on everybody's time by
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    doing that.
               I will give you what my rules of court are in case
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    you are present in court, and I stick with these pretty
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    religiously, and every judge that I know likes an orderly
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    trial. I think I'm sort of in the middle of being controlling
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    or not. I wish to have you have the freedom to present your
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    case but I want it done in an orderly manner.
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              So these are sort of my rules of court and counsel
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    behavior during the trial. You must --
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              MS. BRECHT: Your Honor, may I sit?
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              THE COURT: You may sit.
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              Rule No. 1 is, you must address the witness in one of
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    two ways, either by their last name or by their first and last
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    name together. Don't address a witness only by their first
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           The exceptions to that are minors and to avoid confusion
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    with multiple witnesses having the same last name.
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               If you're in court, you stand when you address the
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    Court even if it is to say a single word.
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              Only one attorney per side can both examine and
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objection.

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object to the other side's examination. So if one attorney examined the witness, co-counsel cannot then object to the other side's examination. Only one attorney does that. That cuts down on the confusion. That's also the case, and I don't think that will be the case in this case, but if we have any 11:38 sidebars, which we won't because its not a jury trial, then one attorney argues the point. I don't want multiple attorneys per side arguing the same point. Obviously, do not walk in the well or allow anybody else to walk in the well. 11:39 Do not bring food into the courtroom. You may bring something to drink, but do not bring food into the courtroom. Do not eat your lunch in the courtroom. There are other places in the courthouse where you can have lunch. If a witness is testifying live, do not approach that 11:39 witness unless you first ask for permission to do so and I grant it. My normal practice is not to let you approach the witness physically but to hand any document or exhibit to my deputy clerk who will then himself hand it to the witness. If you wish to object, you stand and you say the word 11:39 "objection," and you state the legal basis for the objection. You do not argue. Now, in this, I may give you a little more flexibility because the jury is not present, but still, do not argue unless you ask and I give you permission to argue the

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Also, be conscious what is and what is not a legal objection, okay? An objection saying "improper," that's not a legal basis for an objection. You have to give me a legal basis for the objection.

Do not publish an exhibit unless you've first identified it with a unique number, laid its foundation, or told me that the other side agrees to its admission and ask for it to be introduced into evidence. After I introduce it into evidence, you may go ahead and question the witness about the substance of that document.

When court is in session, you must address me and not each other. So do not break into impromptu conversations with opposing counsel even if it is to try to resolve an issue which needs a resolution. What you do is, you ask for permission to confer. I will always grant it. You then confer and tell me what, if anything, has been resolved.

When you are examining a witness or delivering your opening or closing statements, you do so from the lectern. Do not pace back and forth or wherever from the lectern. You must remain at the lectern or within one arm's length of it while you speak.

If you wish to exclude any witnesses then please do so at the beginning of the trial. I typically don't exclude parties or experts during testimony by other witnesses.

So those are the general rules. All the other ones

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    apply to when jurors are present. So be conscious of those
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    rules, and I think the trial will go much more smoothly.
               I intend to issue the ruling on the motions in
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    limine, which you already know what it is, but I'll issue a
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    written ruling probably this week.
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              So is there anything else that we need to discuss
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    before we convene on the 28th?
               If for some reason either side encounters technical
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    difficulties after consulting with my staff which would make it
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    improbable that we can have a smooth trial, then please alert
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    my staff or file some kind of notice of that, and I will
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    consider either postponing the trial or some other measure. I
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    certainly do not want to burden any side from presenting their
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    case. So if the technical difficulties cannot be resolved, I
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    quess I will have to continue the trial, but I do not want to.
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              Anything else by either side that they wish to bring
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    up before we adjourn?
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              MS. BRECHT: Your Honor --
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              MS. SANDERS: Thank you, Your Honor.
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              THE COURT: Let the plaintiff go first. By the
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    plaintiff.
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              MS. SANDERS:
                             Thank you, Your Honor. You touched on
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    a number of points when you were reviewing the rules of court.
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    I just want to flag for Your Honor's consideration that we may
    need to talk about the specifics of a protocol or a plan with
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how you would handle some of those rules of court with the witnesses who are appearing remotely. So, for example, a sidebar, that we want to make sure that the witness isn't able to listen in on or, you know, how we go about presenting exhibits to that witness who is only appearing by video and 11:44 details like that. If Your Honor has a preference for how we bring those kinds of issues to your attention separate and apart from just making sure that the technology works, you know, we will be sure to comply with whatever Your Honor would want us to do. But I do want to make sure that some of those 11:44 things that you mentioned, we are able to be consistent with our virtual witnesses as well as the --THE COURT: I understand. So I think we have the technology to mute the witness video while we discuss other matters, so I think that can be done. But, again, the 11:44 specifics of that you will have to discuss with my clerk and my IT person. As to the exhibits that will be presented and will be introduced through specific witnesses, then I suggest you talk with opposing counsel and have a method by which the exhibit 11:44 that will be received, the witness has a copy and there is some kind of verification that the exhibit which you're introducing is the same one that the witness has with him or her, either by declaration or some other form, and then I think we can proceed

that way. But there has to be some kind of verification,

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preferably under oath, by somebody that the exhibit that is being used by the questioner is the same exhibit that is in front of the witness, but I think those things can be worked out.

Any other concerns?

MS. SANDERS: I do. I do. You also mentioned the importance of being selective with the trial testimony that's presented, and we certainly will be sure to abide by the Court's recommendation there. I do just want to clarify that the Court still intends for the Government to put on all of the evidence underlying the elements of this claim. I know when we posed this question in the motion for clarification, the Court was very clear that it was expecting the Government to put on its entire case, and so I do want to make sure that at the end of our trial process that we have a record that contains evidence on every claim that the Government bears the burden of establishing at trial. That's important in the event that there perhaps may be an appeal taken by either side, we just want to ensure that our record is complete.

THE COURT: Certainly. It's not my intent in any way to limit you or restrict you from doing that, presenting evidence regarding every claim to which you have a burden of establishing. I wasn't referring to that. I was highlighting more sort of what I believe to be irrelevant testimony or repetitive or duplicative testimony since there's going to be

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    multiple witnesses perhaps testifying about overlapping issues.
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              MS. SANDERS: Fair enough. Thank you, Your Honor.
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              And does Your Honor contemplate that the trial will
    be broadcast to the public in some way?
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              THE COURT: No.
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              MS. SANDERS: Okay. Fair enough.
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              THE COURT:
                          I mean, anybody can come in. Its a
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    public trial, but it's not a publically broadcasted trial.
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              MS. SANDERS: Understood. And with respect to
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    information that the parties contend should be protected from
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    disclosure in some way, whether it was confidential commercial
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    information that the defendants may seek to protect or
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    information that is in a patient's medical record and that is
    otherwise subject to nondisclosure, how does the Court prefer
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    that the parties handle that?
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              THE COURT: So the best way I think to handle that is
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    handle it by exhibit by exhibit when the time comes. Perhaps
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    before the witness is going to testify about that particular
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    exhibit then we can have a conversation about what should be
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    sealed and what can remain public. Obviously, there is a
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    preference and a strong preference for public access to the
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    exhibits. It is a public trial after all. But, obviously, if
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    there is some sensitive information of a personal nature, you
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    can either redact that from the exhibit that is to be
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    introduced or have certain portions or all of the exhibit be
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1 introduced under seal. 2 MS. SANDERS: Thank you, Your Honor. Those are all 3 my questions at this time. 4 THE COURT: Very well. For the defendants, any 5 questions, clarifications? 11:48 6 MS. BRECHT: Yes, Your Honor. One issue which Your 7 Honor touched on was the length of the Government's exhibit list, and we've tried to meet and confer with the Government to 8 9 figure out which of the 23 -- I'm sorry, the witness list, not exhibit list. 10 11:49 11 THE COURT: Right. 12 MS. BRECHT: We tried to meet and confer with them to 13 figure out which of the 23 witnesses they actually intend to 14 call just in connection with trial preparation and then also 15 time limits. Is there any deadline that Your Honor could give 11:49 16 or additional guidance or instruction to actually get this list 17 to come down to a reasonable size and/or could we get an order 18 that at least three days in advance of when the Government is 19 going to call these witnesses that we get notice of which 20 witnesses will be called? 11:49 21 THE COURT: So there is a couple of ways that we can address that. One is, you know, I will issue the motions --22 23 the ruling on the motions in limine. That may narrow down the 24 testimony and/or the number of witnesses. The other rule that I generally impose on both sides is to alert the opposing side 25 11:49

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the night before by 6 p.m. of the witnesses that the other side intends to call the following day. So that way you're not in the dark about who may or may not testify. So that would give you some indication. Obviously, they're not going to be able to call 20 witnesses in a day. So if I order them to give you 11:50 an indication who they anticipate calling the next day, you'll have a good idea what witnesses will testify and what their testimony will be having previously deposed those witnesses. MS. BRECHT: Thank you, Your Honor. MS. SANDERS: Your Honor, may I --11:50 THE COURT: Hold on. The defendant is not done. MS. BRECHT: The other issue, in connection with witnesses, is that the Government and the defense have witnesses that overlap. So, as an example, Dr. Lander and Dr. Berman and Sean Berman, and so in hopes of supporting 11:50 efficiency, I would request that whenever the Government calls Dr. Lander, Dr. Berman, and if they call Sean Berman in their case-in-chief, if I could either do my direct examination first or if my examination could be not limited to whatever the scope of the Government's direct is so that each of those witnesses 11:51 is only called once as opposed to being called twice, I think especially because it's a bench trial. THE COURT: Right. So that is granted. Feel free to exceed the scope on the other side. And I will give each side -- what I normally do is, I give each side two examinations per

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witness so you're able to respond. So if the plaintiff calls a
witness, they will direct and redirect, the defendant would
then cross/direct and recross. So you have, both, two shots,
an initial shot at the witness and then a response with a
second examination.
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          MS. BRECHT: Thank you, Your Honor.
          THE COURT: So back to the plaintiff. Ms. Sanders,
do you have any other concerns?
          MS. SANDERS: Well, Your Honor, would you entertain
briefly being heard on the issues that defense counsel just
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raised, because they touch on a number of important points?
          THE COURT: What are your concerns regarding that?
          MS. SANDERS: Okay. So with respect to the idea that
defense counsel will exceed the scope of direct and wish to
question Dr. Berman, Dr. Lander, or any other of the defense
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witnesses beyond the scope of the Government's testimony, this
seems to be an attempt to have the Court rule on their request
for bifurcation. And, Your Honor, we don't think that is
appropriate in this case for a number of reasons.
          Defendants disclosed their witnesses to us as fact
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witnesses, and we intend to perhaps call one or more of them as
fact witnesses. What we don't want to do is have them then lay
out their defense in the middle of our affirmative case.
          Generally speaking, when it comes to issues of
bifurcation, which is what her request really touches on, you
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generally bifurcate by having liability established in the first instance and then, only if that's been established, having someone present a defense or having someone present testimony as damages.

What defense counsel just suggested is that Your Honor put the cart before the horse. In other words, we'll be at a point in our potential examination where we won't have even established that the FDCA has been violated. We are simply trying to get a number of facts on the record so that Your Honor can have a normal examination of the Government's case and actually understand what the Government has alleged with respect to the FDCA claims.

THE COURT: I think the dangers which you highlight would be more salient in a jury trial. I think I can keep straight what goes to the case-in-chief and what goes to a defense and whether or not one or the other or both have been established. So I don't see a danger of having that testimony. I'm not going to be prejudiced by testimony of a defense in determining whether or not you state your case. So I think we're going to do it that way.

If you wish, you have the chance to recall witnesses, so you can, after the testimony is done of your witness, in rebuttal, you may recall a witness if you think something has been missed or something needs to be clarified in light of the examination that the defendants conducted. So you'll have

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plenty of opportunity to make clear what testimony you wish to have the Court pay attention to. And you, as the plaintiff, have the exclusive right to call witnesses on recall. So I think the dangers that you highlight are not going to be real dangers during the trial.

Anything else?

MS. SANDERS: One other point about narrowing down the Government's witness list. We've had a number of conversations off line with defense counsel about the fact that nine witnesses on that list are associated with the defendants, seven of whom are nonparty witnesses, and we have stressed to them on multiple occasions that we don't intend to call those witnesses in our case-in-chief but would purely reserve them for rebuttal in the event that we need them.

We do need to serve subpoenas on those nonparty witnesses. We asked defense counsel if they could accept service of these subpoenas of these individuals that are employees of or otherwise associated with the defendants and they did decline. So I just want to flag for Your Honor that we are working to serve these subpoenas. And first, we just need to figure out the residential addresses of these individuals. We don't have that because we, otherwise, just have their corporate affiliated address, and we requested assistance from opposing counsel in locating these people, but we have not yet --

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              THE COURT: And these are current employees of
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    California Stem Cell Treatment?
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              MS. SANDERS: We understand that most of them are.
 4
    We're not personally aware of who is not.
 5
              THE COURT: Very well. So Ms. Brecht, will you
                                                                      11:56
 6
    accept service of the witnesses that are current employees of
 7
    your client?
              MS. BRECHT: Yes, Your Honor, for current employees.
 8
 9
    The issue is, as I represented to the Government, not all of
10
    the people who they've requested are current employees.
                                                                      11:56
11
              THE COURT: Very well. So that is the ruling.
12
    they are current employees of the defendant then the defendant
13
    will accept service for those employees. If they are not
14
    current employees then you will have to find out how you're
15
    going to serve them.
                                                                      11:57
16
              MS. SANDERS: Thank you, Your Honor.
17
              THE COURT: Anything else?
18
              MS. BRECHT: No, Your Honor.
19
              THE COURT: Very well. Then we'll see you back here
20
    on the 28th. Mr. Galvez will give you contact information for
                                                                      11:57
21
    you to contact -- you and your staff to contact to try to get
22
    the issues resolved regarding the remote testimony and the
23
    video access. And we'll see you back here on the 28th.
24
              Thank you.
25
              MS. BRECHT: Thank you, Your Honor.
                                                                      11:57
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MR. GURVITZ: Thank you, Your Honor.
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                          (Proceedings concluded.)
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1	CERTIFICATE OF OFFICIAL REPORTER
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4	I, PHYLLIS A. PRESTON, FEDERAL OFFICIAL REALTIME
5	COURT REPORTER, IN AND FOR THE UNITED STATES DISTRICT COURT FOR
6	THE CENTRAL DISTRICT OF CALIFORNIA, DO HEREBY CERTIFY THAT
7	PURSUANT TO SECTION 753, TITLE 28, UNITED STATES CODE THAT THE
8	FOREGOING IS A TRUE AND CORRECT TRANSCRIPT OF THE
9	STENOGRAPHICALLY REPORTED PROCEEDINGS HELD IN THE
10	ABOVE-ENTITLED MATTER AND THAT THE TRANSCRIPT PAGE FORMAT IS IN
11	CONFORMANCE WITH THE REGULATIONS OF THE JUDICIAL CONFERENCE OF
12	THE UNITED STATES.
13	
14	
15	DATED THIS 23RD DAY OF JULY, 2020
16	
17	
18	/s/ PHYLLIS A. PRESTON
19	
20	PHYLLIS A. PRESTON, CSR No. 8701, FCRR
21	FEDERAL OFFICIAL COURT REPORTER
22	
23	
24	
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